REMARKS

In the amendments above, Claim 20 has been amended, and new Claims 33 to 39 have been added, to more particularly point out and distinctly claim Applicant's invention. Support for new Claims 33 to 39 can be found, for example, in Claims 20 to 32.

Claims 20-28, 30 and 31 have been rejected under 35 U.S.C. § 102(e) as being anticipated by the Saab patent. The Examiner maintains that Saab shows a catheter (10) for intravascular corporeal cooling comprising: an elongated tubular member (12) having proximal and distal sections, an outer surface, and at least one lumen (11) extending therethrough, and annular insulation (16, 22) having proximal and distal ends arranged concentrically (Fig. 1) around the outer surface of the elongated tubular member (12) is insulated from fluid or tissue external to the annular insulation (16, 22), wherein the insulation is tapered (at 18), extends along substantially the whole length or a shorter section of the catheter and comprises a fluid-filled member, filled with gas, water or saline and polymeric material (14, 20). The Examiner also maintains that with regard to Claim 30, the structure can be used for brain cooling.

Claims 20-24, 27 and 30-32 have been rejected under 35 U.S.C. § 102(e) as being anticipated by the Ginsburg patent. The Examiner maintains that Ginsburg shows a catheter for intravascular corporeal cooling comprising: an elongated tubular member (20) having proximal (24) and distal (26) sections, an outer surface, and at least one lumen (28) extending therethrough, and annular insulation (18, 32, 34) having proximal and distal ends arranged concentrically (Fig. 2) around the outer surface of the elongated tubular member (20) is insulated from fluid or tissue external to the annular insulation, wherein the insulation is tapered (Fig. 11) and comprises a fluid-filled member, and at least one lumen is in communication with a source of cooled blood and/or a liquid pharmaceutical source, which can be used for brain cooling.

Claim 29 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over the Ginsburg patent in view of the Donlon patent. The Examiner maintains that Ginsburg shows all of the limitations of Claim 29 except for the pressure sensor; that Donlon shows a similar catheter for placement in a blood vessel which includes a pressure sensor (38); and that it would have been obvious to one of ordinary skill in the art at the time of the invention to use a pressure sensor in the device of Ginsburg to prevent injury by which can be caused by high pressure fluids in the bloodstream.

Applicant respectfully transverses the above rejections under Sections 102(e) and 103(a).

As set forth, for example, in Claim 20, Applicant's invention is directed to a catheter for intravascular corporeal cooling that comprises an elongated tubular member having annular insulation. When blood, especially cooled blood, flows through a lumen in the catheter, the blood is insulated from fluid or tissue external to the annular insulation, to maintain the temperature of the blood as it flows through the lumen.

While there may be some structural similarities between the invention claimed here and the teachings of the prior art, there are also significant differences. Saab, for example, teaches away from Applicant's invention. Saab teaches a catheter apparatus that provides active heat transfer for the purpose of controlling delivery or withdrawal of thermal energy to or from internal body locations (see, for example, Abstract; Col. 1, lines 15-21; Col. 5, lines 4-14; Col. 6, lines 34-56; Col. 7, lines 7-19). Saab requires materials with good heat transfer properties to allow the temperature of the fluid inside the catheter to be transferred to adjacent portions of the body that are in contact with or in proximity to the catheter sidewalls (Col. 5, lines 20-27). In contrast, Applicant's invention insulates the portion of the body in contact with or in proximity to the catheter sidewalls, i.e., it prevents heat transfer. Saab specifically teaches away from Applicant's invention (Col. 6, lines 20-27).

In addition, Saab teaches a closed loop system whereby the fluid used to cool or heat does not have direct body contact and specifically teaches against a system where any portion of the fluid could remain in the body (Col. 3, lines 42-52; Col. 7, lines 11-19). 8:28-30

Ginsburg teaches an apparatus that actively alters the temperature of a fluid that is to be delivered to a target location while the fluid is within the catheter (Col. 1, lines 6-11; Col. 2, lines 28-30; Col. 8, lines 1-3). The apparatus contains a temperature-altering mechanism disposed within the catheter body which heats or cools the luminal wall to alter the temperature of fluid passing through the lumen (Col. 2, lines 36-48; Col. 3, lines 28-45). This teaches away from Applicant's invention wherein insulation is provided to prevent the temperature of the blood passing through the catheter lumen from being altered. More particularly, elements 18, 32, and 34 in Figs. 2 and 4 of Ginsburg are not annular insular insulation, as suggested by the Examiner. Rather, these are examples of temperature-altering mechanisms (Col. 5, lines 23-27; Col. 5, lines 55-60; Col. 6, lines 14-34). * not claimed

The embodiment shown in Fig. 11 of Ginsburg depicts another means for heat transfer and not tapered insulation (Col. 7, lines 51-60). Ginsburg does not teach an apparatus or device having at least one lumen in communication with a source of e.g. cooled blood, which can be used for brain cooling, instead, he teaches methods and apparatus that alter the temperature of the blood/fluid in situ, i.e., within the catheter before reaching a target location (Col. 5, lines 5-12; Col. 8, lines 1-13).

In sum, whereas there may be some structural similarities between the invention claimed here and the teachings of the cited prior art, there are significant and fundamental differences. More significantly, the devices disclosed in the Saab and Ginsburg patents are directed to catheters that promote heat transfer so that fluid in an inner lumen is heated or cooled by heat transfer from fluid circulated exterior to the lumen. Saab

teaches a catheter apparatus that actively cools or heats body portions that are in contact with or in proximity to the sidewalls of the Saab catheter. Ginsburg teaches an apparatus that actively alters the temperature of a fluid within the catheter. Such teachings are opposite to that of Applicant's invention, in which there is no transfer of thermal energy (heating or cooling) within the catheter, and any cooling or heating occurs distal to the catheter.

It should be noted that the Donlon patent does not overcome the deficiencies of the Saab or Ginsburg patent. Donlon does not show or teach a pressure sensor at or adjacent to the distal end of the catheter. Rather, Donlon teaches incorporating a prior art method for monitoring pressure whereby two pressure sensing lumens are used to communicate with a pressure monitor that is connected to the proximal end of the catheter. (See, Fig. 1)

As said above, the prior art devices taught promote heat transfer. It should be appreciated that the systemic cooling such as taught by the prior art has the disadvantage than if a patient's blood temperature is lowered too much, cardiac problems may ensue.

Thus, the cited patents do not disclose or suggest Applicant's invention. Therefore, the rejections under Section 102(e) and 103(a) should be withdrawn.

Reconsideration and allowance of the claims herein are respectfully requested.

Respectfully submitted,

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